

### **REMARKS**

Applicants have amended Claims 1, 4-5, 7, 30, and 33-34, and have canceled Claims 2-3 and 31-32 without prejudice. Enabling support for the amendments can be found in the application as filed, and therefore no new matter is contained in the amendments. Reconsideration of the present application and allowance of resulting Claims 1, 4-9, 21-25, 27, 30, and 33-38 is respectfully requested in view of the amendments and following remarks.

#### **I. Claim Rejections under 35 U.S.C. § 112, first paragraph, written description requirement**

The Office Action has rejected Claims 1-9, 21-25, 27, and 30-38 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The previous Office Action states that “the claims are broadly drawn to polynucleotides comprising a multitude of somatic tissue-preferred promoters, including leaf-, root-, meristem-, and tuber-preferred promoters, from a multitude of plant and gene sources and of a multitude of sequences; methods for their use; and plant cells and plants transformed therewith. In contrast, the specification provides no guidance for the characterization or description of any somatic tissue-preferred promoter in terms of sequence or gene source, and no plant cell or plant transformed with any of said promoters was reduced to practice.” Applicants respectfully traverse this rejection as follows.

Claims 2, 3, 31, and 32 have been cancelled, and therefore the rejection is moot with respect to those claims.

Claims 1 and 30 of the present application have been amended to incorporate the limitations that the recombinase be a phiC31 irreversible recombinase, and that somatic tissue-

preferred promoter be a plant somatic preferred promoter. These amendments narrow Claims 1 and 30 and also narrow the remaining dependent claims, 4-9, 21-25, 27, and 33-38.

Applicants are not required to isolate and identify every plant tissue-preferred promoter. Applicants have developed self-excising polynucleotide constructs useful in plant tissues. The exact structure of the somatic tissue-preferred promoter will differ with the promoter selected, however, the use of a particular promoter is not critical to the nature of the invention. Any somatic tissue-preferred promoter can be used in the instant invention. The identification of plant promoters for use in the self-excising polynucleotide is routine for one of ordinary skill in the art, and is set out in the instant specification at paragraphs 51 and 52.

The Office Action states "most of the tissue-specific promoters listed in the specification are seed-specific or fruit-specific, rather than somatic tissue-preferred." Applicants assert that they have disclosed at least 6 somatic tissue-preferred promoters, including, for example, promoters from the *lpt1*-gene, the 1,5-ribulose biphosphate carboxylase small subunit genes of *Arabidopsis thaliana* (the "ssu" promoter), the maize phosphoenol pyruvate carboxylase gene, the small submit ribulose bis-carboxylase (ssRUBISCO) gene, the chlorophyll a/b binding gene, and a pith-specific promoter, such as the promoter isolated from a plant TrpA gene. Additional somatic tissue-preferred promoters are readily available and identifiable by one of ordinary skill in the art.

If the specification is read in light of the knowledge and level of skill in the art, the specification discloses the steps of the claimed process and the elements of the claimed composition. As stated by the Federal Circuit "an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains." *In re Hayes Microcomputer Products Inc. Patent Litigation*, 982 F2d.

1527, 1534-35 (Fed. Cir. 1992). Certain areas of biotechnology such as the art of recombinant DNA technology are generally regarded as highly predictable with a high level of skill, such that the selection of a promoter that is somatic tissue-preferred is well within the routine skills of one skilled in the art. The prior art provides numerous examples of somatic tissue-preferred promoters from a wide variety of plants. In the instant application, somatic tissue-preferred promoters are described in the specification, are conventional in the art, and are known to one of ordinary skill in the art (See e.g., Specification page 19, paragraphs 51 and 52). The selection of somatic tissue-preferred promoters is sufficiently developed so as to put one of skill in the art in possession of the steps of the method and the elements of the composition. In other words, one skilled in the relevant art would understand what is intended by the claimed invention and how to carry it out.

The Office Action further states that “a correlation between structure (i.e. gene sequence) and function (i.e. somatic tissue-preferred gene expression) must be demonstrated in order to provide an adequate written description.” The Office Action cited MPEP Section 2163, stating “A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” (Emphasis added). Applicants respectfully assert that this rejection is misplaced, since the claims are not directed to a particular polynucleotide sequence; rather, the claims are directed to a construct describing a particular way of combining types of sequences (promoters, trait polynucleotides, recombinase polynucleotides, and corresponding recombination sites). The claims are therefore directed to a novel combination of known types of sequences, and are not drawn to a particular sequence. As such,

Applicants are not required to disclose every possible sequence that can be used interchangeably in the claimed polynucleotide constructs. The novelty of the invention does not lie in the particular sequence used, but lies in the structure of the construct.

For at least the foregoing reasons, and considering the amendments to the claims, Applicants respectfully request reconsideration and removal of the rejection and allowance of Claims 1, 4-9, 21-25, 27, 30, and 33-38.

## **II. Claim Rejections under 35 U.S.C. § 112, first paragraph, enablement requirement**

The Office Action has rejected Claims 1-9, 21-25, 27, 30-31, and 35-38 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Office Action states that “the specification, while being enabling for claims limited to polynucleotides comprising a plant somatic tissue-specific promoter ligated to a gene encoding a phiC31 recombinase for controlled excision of desired trait polynucleotides in plants, does not reasonably provide enablement for claims broadly drawn to any irreversible recombinase system or animal transformation constructs or systems.”

Claims 2, 3, and 31 have been cancelled, and therefore the rejection is moot with respect to those claims.

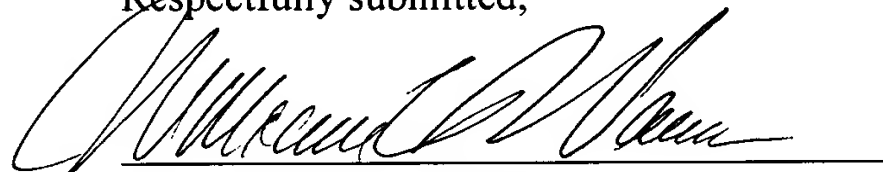
Applicants have amended Claims 1 and 30 such that the claims are now directed to polynucleotides comprising a plant somatic tissue-preferred promoter ligated to a gene encoding a phiC31 recombinase. As such, Applicants assert that the amendments overcome the rejection, and respectfully request reconsideration and removal of the rejections and allowance of Claims 1, 4-9, 21-25, 27, 30, and 33-38.

For at least the foregoing reasons, Applicants respectfully request reconsideration and removal of the rejections and allowance of Claims 1, 4-9, 21-25, 27, 30, and 33-38. The foregoing is submitted as a full and complete Response to the Final Office Action mailed December 9, 2003.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 19-5029.

This Response places all claims in the present application in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William L. Warren', is written over a horizontal line.

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